JUDGE HAIGHT

07 CV 10376

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

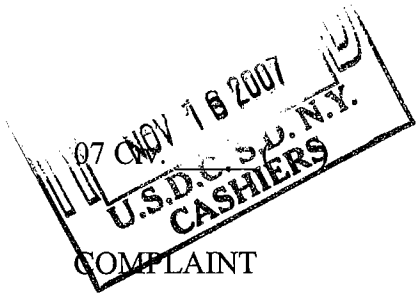
KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff,

- against -

PANION & BF BIOTECH, INC.,

Defendant.



COMPLAINT

Plaintiff Keryx Pharmaceuticals, Inc. ("Keryx"), by its attorneys, for its Complaint in this action, alleges as follows:

NATURE OF ACTION

1. This is an action for declaratory and injunctive relief and damages arising from the threatened termination of a license agreement under which defendant Panion & BF Biotech, Inc. ("Panion") granted Keryx exclusive rights to develop and commercialize a licensed pharmaceutical product for treatment of kidney disease. Panion's asserted basis for terminating the license agreement is incorrect. Moreover, in conjunction with its improper termination threats, Panion has breached the license agreement by attempting to prevent Keryx from developing the licensed product and has tortiously interfered with Keryx's ongoing contractual relations with third parties

who are assisting Keryx in developing the licensed product. Panion's actions threaten to cause Keryx irreparable harm.

PARTIES AND JURISDICTION

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with its principal place of business at 750 Lexington Ave., 20th Floor, New York, NY 10022.

3. Upon information and belief, Panion is a corporation organized and existing under the laws of Taiwan, having an office in Queens County, New York and its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.

4. This action arises under the common law of the State of New York and the Declaratory Judgments Act, 28 U.S.C. §§ 2201 et seq.

5. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(a). The parties are of diverse citizenship, and the amount in controversy exceeds the sum or value of seventy-five thousand dollars ($75,000), exclusive of interest and costs.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a).

BACKGROUND

7. Keryx is a pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious and life-threatening diseases, including diabetes, cancer, and renal (kidney) disease.

The License Agreement

8. Panion is the owner or exclusive licensee of certain patents and patent applications, including U.S. Patent No. 5,7753,706, issued May 19, 1998, for an invention entitled "Methods For Treating Renal Failure" (the "Hsu Patent"). The Hsu Patent describes and claims a method of controlling phosphate retention in patients suffering from elevated phosphate levels by administering a therapeutically effective amount of ferric citrate. Phosphate retention leading to elevated phosphate levels is a common and serious complication of advanced renal disease.

9. Keryx and Panion are parties to a license agreement, dated November 7, 2005 (the "License Agreement") whereby Panion (Licensor) granted to Keryx (Licensee) an exclusive license under the Hsu Patent, its corresponding foreign counterparts, and other Panion-owned or Panion-controlled patents and patent applications, to develop and commercialize ferric citrate and pharmaceutical products containing ferric citrate as an active ingredient (collectively, the "Product") throughout most of the world, including but not limited to the United States, Canada and Japan, for treatment of renal disease.

10. Section 3.1 of the License Agreement provides:

> Grant. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive license, in the Territory, with the right to sublicense, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product in the Territory under the Licensor Know-How, and the Patent Rights for all Indications in the Field.

11. As defined in Section 1.13 of the License Agreement, the term "Licensor Know-How" includes:

> discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise, in each case, which as of the Effective Date and during the term of this Agreement are necessary or useful to Licensee in connection with the development, registration, manufacture, marketing, use or sale of a Product.

12. Section 7.7 of the Agreement provides, in part:

> Both parties agree to work in good faith to fully collaborate to review and administer the manufacturing program for the Compound and to resolve any technical issues both immediately after the Effective Date and at least annually thereafter during the Exclusive Supply Period as defined below.
>
> For the period commencing on the Effective Date and continuing for three (3) years following Registration in the United States (the "Exclusive Supply Period"), Licensee (and its Sublicensees) shall obtain their supply of the Clinical Supplies and of the Compound exclusively from Licensor. In consideration for such supply, Licensee shall provide compensation to Licensor at fifteen percent (15%) over Licensor's manufacturing and procurement cost. Notwithstanding the preceding two sentences, decisions and actions related to pharmaceutical development and manufacturing of the Clinical Supplies are subject to joint review and approval. During the Exclusive Supply Period, Licensee shall be entitled to engage an alternative supplier of Clinical Supplies of the Compound provided that (i) Licensee has demonstrated to Licensor that the Clinical Supplies or the Compound subject to this Section 7.7(b) can be made available to Licensee by an alternative third-party supplier at a price that is more than 25% below what Licensor charges Licensee in accordance with this Section 7.7(b); and (ii) Licensor within sixty (60) days thereafter fails to meet the price offered by such alternative supplier.

13. After entering into the License Agreement, Keryx and Panion began discussing the development of improved processes and specifications for manufacturing, at commercially reasonable cost, Active Pharmaceutical Ingredient

("API") containing pharmaceutical-grade ferric citrate suitable for treatment of human patients suffering from advanced renal disease. A supply of API is indispensable for performing the preclinical testing and clinical trials that are needed to obtain regulatory approval from the Federal Food and Drug Administration ("FDA") and its foreign counterparts to commercialize pharmaceutical agents containing ferric citrate.

Panion's Acquiescence in Keryx's Orders of API

14. On July 26, 2006, Keryx sent an email to the President of Panion detailing an urgent need for 100kg of API to be sent under the conditions of the contract to begin critical path toxicology studies. Instead of responding in an urgent manner in spite of Keryx's repeated requests to supply quantities as low as 5 kg immediately so it could begin those studies, Panion introduced Keryx to its previous contractor, BRI Biopharmaceutical Research Inc. ("BRI"), located in Vancouver, Canada, for the purposes of organizing supply but then declined to participate in any planning, saying that it just wanted to be kept informed. Keryx kept Panion informed of its development program by emails and progress reports, and invited Panion to attend meetings with BRI, which Panion declined on the grounds that "Panion is a small company with limited budget and resources."

15. BRI introduced Keryx to BioVectra DCL ("BioVectra"), located in Prince Edward Island, Canada, and through BioVectra to a subcontractor, the PharmPro Services division of Fluid Air, Inc., ("PharmPro"), located in Aurora, IL. Working with BRI, BioVectra and PharmPro, Keryx has incurred significant expenditures and devoted substantial corporate resources to the development of specifications and manufacturing processes for API. Not until September 1, 2006, did Panion respond definitively that it had "checked the inventory and found out we don't have any quantity in stock."

16. On September 5, 2006, Keryx placed a purchase order with BioVectra for the manufacture of 400 kg of API, in 3 lots, under a quotation that Panion had requested Keryx to obtain and that had been emailed to Keryx, with a copy to Panion, on August 24, 2006. Despite its awareness of the impending order for production, Panion did not object to Keryx or offer to participate in any active way.

17. On September 11, 2006, Keryx emailed Panion offering to increase its order for API to cover any needs that Panion might have. Without objecting to Keryx's order or offering to take over the work of coordinating the production, Panion responded that it had sufficient API for its own purposes. After receiving Panion's response, Keryx ordered a fourth batch of API from BioVectra. Panion continued to be copied on emails periodically over the coming month and a half until production began, and then over the subsequent two months on discussions of changes in specifications and controls. At no time did it raise any objection to the fact that Keryx and BRI were working together to coordinate the production or offer

to participate in any active way. The four batches of API have been manufactured and title has passed to Keryx.

18. In February, 2007, after the production and formal release of the product for use, Keryx and Panion exchanged correspondence and finally a formal letter of understanding regarding regulatory reporting of the results of the production. At no time did Panion object to the fact that Keryx had organized the production and paid for it directly.

19. Both prior to the production and in the nine months thereafter Keryx has contracted and borne the entire expense for additional development work by BRI, BioVectra and PharmPro aimed at improving the efficiency (i.e., lowering the cost and increasing the yield) of producing API and assuring its stability. The continuing development work will not result in Keryx being supplied with additional API over and above the four lots that Keryx previously ordered. Keryx has now made a substantial investment in lowering the cost of manufacturing which is a critical component of commercializing ferric citrate (i.e., the development of a commercially feasible, cost-effective process for manufacturing pharmaceutically pure API suitable for clinical trials and commercial sale).

The Japanese Sublicense

20. On September 26, 2007 Keryx concluded an agreement (the "Sublicense") with Japan Tobacco, Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii") by which Keryx granted to JT and Torii an exclusive sublicense under the License Agreement to develop and commercialize ferric citrate in Japan, in exchange for an initial licensing fee of $12 million plus future milestone and royalty payments.

Under the License Agreement, Panion is not entitled to share in the initial licensing fee or milestone payments.

Panion's Threatened Termination and Interference With Licensed Activities

21. On October 31, 2007 Panion's counsel sent Keryx an email contending that Keryx's purchases of API, under contracts entered into a year earlier, constituted a "material breach" of the Licensing Agreement that "has not been cured for more than ninety days" and threatening to take "appropriate actions to nullify the agreement." The License Agreement gives Panion (Licensor) a right to terminate for cause "upon or after the breach of any material provision . . . by Licensee if such breach is not cured within ninety (90) days after Licensor gives Licensee written notice thereof . . . ." No prior written notice of any alleged breach of the Licensing Agreement had been given to Keryx before October 31, 2007.

22. On or about November 8 and 9, 2007, Panion accused BRI, BioVectra and PharmPro of making improper use of Panion-owned technology and threatened to commence legal action against them unless they discontinued their contractual activities for Keryx.

23. On November 12, 2007, Keryx's counsel wrote to Panion's counsel pointing out that Panion had acquiesced in Keryx's prior purchases of API, stating that Keryx had no pending unfilled orders for supply of API, agreeing that Keryx would submit future purchase orders for supply of API to Panion in accordance with Section 7.7 of the License Agreement, and demanding that Panion cease and desist from threatening Keryx's contractors and that Panion retract the demands and allegations it had issued to them.

24. On November 13, 14 and 15, 2007, Panion's counsel again contacted PharmPro, BRI and BioVectra, respectively, again threatening that Panion would commence legal action unless they discontinued their contractual activities for Keryx.

25. On November 15, 2007, Panion filed a Summons with Notice in Queens County, New York asserting claims against BRI.

FIRST CAUSE OF ACTION
(Breach of contract)

26. Paragraphs 1-25, above, are realleged and incorporated by reference as if set forth in full.

27. Under the License Agreement, Panion has authorized Keryx to use Panion-owned technology to "develop [and] have developed" API containing pharmaceutical-grade ferric citrate.

28. The threats and demands issued by Panion against BRI, BioVectra and PharmPro constitute a breach of Keryx's rights under the License Agreement to develop API.

29. Panion's conduct, unless enjoined, will cause Keryx irreparable harm for which it has no adequate remedy at law.

SECOND CAUSE OF ACTION
(Tortious interference with contractual relations)

30. Paragraphs 1-29, above, are realleged and incorporated by reference as if set forth in full.

31. By demanding that BRI, BioVectra and PharmPro cease the development activities they are performing under contract to Keryx, Panion has tortiously interfered with the ongoing contractual relationship between Keryx and

BRI, BioVectra and PharmPro. Panion has made these demands knowing that they are contrary to the rights granted Keryx under the License Agreement and for the purpose of harming Keryx.

32. Unless enjoined, Panion will continue to interfere with Keryx's contracts with BRI, BioVectra and PharmPro.

33. Panion's conduct threatens Keryx with irreparable harm for which it has no adequate remedy at law.

THIRD CAUSE OF ACTION
(Declaratory judgment that Keryx has not breached the License Agreement)

34. Paragraphs 1-33, above, are realleged and incorporated by reference as if set forth in full.

35. Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro did not breach the License Agreement, among other reasons, because Panion acquiesced in and consented to those purchases.

36. Panion is estopped from contending that Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro constitute a breach of the License Agreement.

37. Moreover, any alleged breach by virtue of Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro did not materially breach the License Agreement.

38. A ripe, justiciable controversy exists between Panion and Keryx concerning whether Keryx has breached the Agreement by purchasing four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro.

FOURTH CAUSE OF ACTION
(Anticipatory breach)

39. Paragraphs 1-38, above, are realleged and incorporated by reference as if set forth in full.

40. Section 12.3.1. of the License Agreement prohibits Panion from terminating the License Agreement for a material breach unless and until Keryx has failed to cure the breach within ninety (90) days after Panion has given Keryx written notice thereof.

41. In its initial notice dated October 31, 2007, Panion stated that Keryx's alleged material breach "has not been cured for more than ninety days" and threatened to take "actions to nullify th[e] agreement." Panion thereby breached the termination clause of the License Agreement by failing to give Keryx ninety days after notice to cure the alleged breach.

42. Panion is not entitled to terminate the License Agreement and its threat to do so breaches the express provisions thereof .

43. Panion's conduct threatens Keryx with irreparable harm for which it has no adequate remedy at law.

FIFTH CAUSE OF ACTION
(Breach of contract)

44. Paragraphs 1-43, above, are realleged and incorporated by reference as if set forth in full.

45. Section 8.1.1 of the License Agreement provides:

> Licensor shall use reasonable efforts to prosecute the patent applications included in the Patent Rights . . . Licensor shall regularly consult with Licensee and shall keep Licensee advised of the status of all patent

> applications and patents relating to the Patent Rights by providing Licensee with copies of such patent applications and patents and copies of all patent office correspondence relating thereto including any office actions received by Licensor and responses or other papers filed by Licensor. Licensor specifically agrees to provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Licensor any proposed response thereto. Licensor further agrees to provide Licensee with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult on all proposed responses to patent office correspondence relating to such patent applications and patents.

46. Keryx has repeatedly requested Panion to provide a comprehensive docket report on the Patent Rights licensed to Keryx under the License Agreement. Panion has neither provided the requested docket report, nor provided any explanation for its failure to comply with these requests.

47. On or about August 28, 2007, the Japanese Patent Office issued a Notice of Office Action concerning the Japanese counterpart of the Hsu Patent.

48. Panion initially permitted its Japanese patent counsel to collaborate with the patent counsel of Japan Tobacco, Keryx's sublicensee, in evaluating the Notice of Office Action and determining how to prepare a response.

49. On information and belief, it was agreed at the meeting between Panion's and Japan Tobacco's patent counsel that a 3-month extension should be sought so that Japan Tobacco could undertake a comprehensive search to identify and analyze published articles that support the patentability of the claimed subject matter.

50. On October 24, 2007, Panion's counsel notified Keryx that Panion would request a 3-month extension. The very next day, October 25, 2007, Panion's counsel sent Keryx a further email in which Panion refused to seek the extension

"based on the unresolved issues between Keryx and Panion." Panion also instructed its Japanese patent counsel to stop interacting with the patent counsel of Japan Tobacco.

51. Panion has breached the License Agreement by failing to consult in good faith with Keryx concerning prosecution of the licensed patent applications and by failing to keep Keryx informed of the status of the licensed patents and patent applications.

52. Panion's conduct has damaged Keryx.

WHEREFORE, Keryx demands judgment as follows:

1. Declaring that:

   a) Keryx is not in breach of the License Agreement;

   b) the alleged breach concerning orders for supply of API is not material;

   c) Keryx has until January 30, 2008 to cure any alleged breach concerning orders for supply of API; and

   d) any notice by Panion purporting to terminate the License Agreement is null and void;

2. Preliminarily and permanently enjoining:

   a) Panion from issuing a notice to terminate the License Agreement before Keryx's time to cure any alleged breach has expired; and

b) Panion from taking any action to interfere with Keryx's rights under the License Agreement, including its right to contract with third parties to develop the Product;

3. Directing Panion to pay damages to Keryx in an amount to be determined at trial, with interest thereon;

4. Awarding Keryx punitive damages on its claim for tortious interference;

5. Awarding Keryx its costs and disbursements (including expert and attorneys' fees incurred in this action); and

6. Awarding Keryx such other and further relief as the Court may deem just and proper.

Dated: New York, New York
November 16, 2007

FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP

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